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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/912,266 | 07/24/2001 | James E. Fleming | 390054.402 | 4134 |
| 500 | 7590 | 10/03/2003 | EXAMINER | |
| SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092 | | | GABEL, GAILENE | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1641 | 11 | |
| DATE MAILED: 10/03/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------|---------------------|
| Office Action Summary | Applicant No. | Applicant(s) |
| | 09/912,266 | FLEMING ET AL. |
| Examiner | Art Unit | |
| Gailene R. Gabel | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9-24,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 9-24,27 and 28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed 6/3/03 in Paper No. 10 is acknowledged and has been entered. Claims 9, 12, 15-17, 20, 23, 27, and 28 have been amended. Currently, claims 9-24, 27, and 28 are pending and are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12, 17, 20, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 lacks antecedent support in reciting, "the total cell count."

Claim 17, as amended, is vague and indefinite because it is still unclear what is encompassed by the recitation of "a value", albeit indicating the relative number of viable cells to non-viable cells". Does Applicant intend "a value" to be a ratio. Alternatively, it is unclear how a relative number of viable cells to non-viable cells is obtained in the absence of 1) detection of the number non-viable cells or 2) detection of a total of all viable and non-viable cells.

Claim 17 lacks clear antecedent support in reciting, "the detected viable cell value."

Claim 17, lines 4-6 remains confusing because it is unclear how correlating the number of detected viable cells with a standard value provides a quantitation of the number of viable cells in the sample, when the mere detection of the enzymatically altered dye in viable cells, i.e. "detecting the number of viable cells", would have readily and already provided the quantitation of the viable cells in the sample, which is what is required by the preamble. Accordingly, it is unclear what is intended by the correlation step in the claim.

Claim 20 lacks antecedent support in reciting, "the total cell count."

Claim 27 lacks antecedent bases in reciting, "the method".

Regarding claim 27, the phrase "or other methods of counting" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "or other methods"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

Claim 27 remains confusing because it is unclear how "instructions for carrying out a method" correlates to "hemocytometer counts, plate counts, or other ...". Does Applicant intend that results obtained from use of the kit correlates to hemocytometer counts....

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9-12, 14, 15, 17-20, 22, and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Breeuwer et al. (Applied and Environmental Microbiology 60(5): 1467-1472 (May 1994) for reasons of record.

4. Claims 9, 11, 12, 14, 16, 17, 19, 20, 22, 24, 27, and 28 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sarkadi et al. (US 6,277,655) for reasons of record.

5. Claims 13 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Breeuwer et al. (Applied and Environmental Microbiology 60(5): 1467-1472 (May

1994) or Sarkadi et al. (US 6,277,655) in view of Katz (US 3,586,859) for reasons of record.

Response to Arguments

6. Applicant's arguments filed 6/3/03 have been fully considered but they are not persuasive.

A) Applicant contends that Breeuwer et al. does not anticipate the claimed invention because Breeuwer et al. only disclose determining the metabolizing capacity (vitality) of a yeast cell population. Applicant specifically argues that Breeuwer et al. do not teach determining both viable cell count and total cell count (viable and non-viable cells) and comparing counts therebetween in a sample, as recited in the claimed invention.

Contrary to Applicant's argument, Breeuwer et al. indeed, teach detecting viable cells or determining cell viability in yeast cell populations (see Title and Abstract). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., determining both viable cell count and total cell count (viable and non-viable cells) and comparing counts therebetween in a sample) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

B) Applicant contends that Sarkadi et al. does not anticipate the claimed invention because Sarkadi et al. does not teach detecting or quantitating viable cells compared to total cell count as recited in the claimed invention. Applicant specifically argues that the method of Sarkadi et al. measures only viable cells that possess active multi-drug resistance membrane proteins; thus viable cells that do not possess the multi-drug resistance membrane proteins will not be detected by Sarkadi et al.

Contrary to Applicant's argument, Sarkadi et al. indeed, teach detecting viable cells or quantitating viable cells versus non-viable cells. To reiterate, Sarkadi et al. disclose contacting cells with non-fluorescent form of calcein AM dye that diffuses into cell where the dye is detectably altered into a fluorescent form, i.e. free calcein, by intracellular esterase enzymes, without the necessary presence of active multi-drug resistance proteins (see column 10, lines 53-67). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., determining both viable cell count and total cell count (viable and non-viable cells) and comparing counts therebetween in a sample) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

C) Applicant argues that the combination of Breeuwer et al. or Sarkadi et al. with Katz does not suggest or render obvious the claimed invention. Applicant specifically argues that Breeuwer et al. and Sarkadi et al. do not teach detecting or quantitating

viable cells compared to a total cell count and Katz does not remedy such deficiency, since Katz discloses only a method of detecting non-viable (dead) cells whereas the claimed invention detects viable cells.

In response to applicant's argument that Breeuwer et al. and Sarkadi et al. fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., detecting or quantitating viable cells compared to total cell count) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion or motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Breeuwer et al. and Sarkadi et al. both teach detecting viable cells or determining cell viability in cell populations as recited in the claimed invention. Katz was incorporated thereto only for the teaching of determining viable cell count in comparison to total cell count using UV absorption measurement. Specifically, Katz discloses counting non-viable (dead) cells, killing all the cells, then obtaining a total count of the cells wherein a difference between the total count and non-viable cell count is the total viable cell count.

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See Abstract and Summary. Thus, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Katz in determining specifically the total count of cells including both viable cells and non-viable cells using UV absorption measurements, into the method of determining the amount of viable cells in a sample as taught by Breeuwer or Sarkadi because Katz specifically taught that a total amount of both viable and non-viable cells can be obtained by first measuring non-viable cells, the difference of which is reflective of the number of viable cells, then killing the viable cells using heat in order to obtain a total count of all the cells in the sample using UV absorption measurements.

7. For reasons aforementioned, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0169.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
September 25, 2003

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Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641